

WHAT IS CLAIMED IS:

1. A pharmaceutical composition for the controlled release of a drug in the form of a perforated tablet, the pharmaceutical composition comprising one or more than one enteric polymer and a drug, where the enteric polymer is substantially hydrophobic and substantially
5 soluble in a substantially aqueous environment above a pH of about 5.

2. The pharmaceutical composition according to claim 1, where the pharmaceutical composition comprises a plurality of layers, where one or more than one of the plurality of layers is a substantially water-insoluble polymer, or a substantially water-soluble polymer, and where one or more than one of the plurality of layers comprises an enteric polymer and a drug.

3. The pharmaceutical composition according to claim 1, where the form of the perforated tablet is a cylindrically shaped tablet, and where the perforation extends completely through the center of the cylindrically shaped tablet.

4. The pharmaceutical composition according to claim 1, where the one or more than one enteric polymer is selected from the group consisting of a hydroxypropylmethylcellulose acetate succinate, a hydroxypropylmethylcellulose phthalate, a polyvinylacetate, and a
15 polyacrylate.

5. The pharmaceutical composition according to claim 3, where the one or more than one enteric polymer is a polyacrylate selected from the group consisting of an acrylate polymer, a methacrylate polymer, a methylmethacrylate polymer, an ethylacrylate polymer, a
20 copolymer comprising a combination of the preceding polymers, and a carboxylic acid functional group containing derivative of the preceding polymers and copolymers.

6. The pharmaceutical composition according to claim 4, where the one or more than one enteric polymer is a polyacrylate selected from the group consisting of a methacrylic acid-methylmethacrylate copolymer and a methacrylic acid-ethylacrylate copolymer.

7. The pharmaceutical composition according to claim 1, where the one or more than one enteric polymer is present in an amount effective to control the release of the drug at a substantially constant linear rate over time, or a slightly increasing linear rate over time, or a slightly decreasing linear rate over time.

8. The pharmaceutical composition according to claim 1, where the enteric polymer is present in an amount of between about 1% and about 99%.

9. The pharmaceutical composition according to claim 1, where the enteric polymer is present in an amount of between about 20% and about 75%.

5 10. The pharmaceutical composition according to claim 1, where the enteric polymer is present in an amount of between about 35% and about 65%.

11. The pharmaceutical composition according to claim 1, additionally comprising one or more than one binder.

10 12. The pharmaceutical composition according to claim 11, where the binder is selected from the group consisting of a water-soluble cellulose, a polyethylene oxide, a polyethylene glycol, a water-insoluble cellulose, a water-insoluble polyvinylacetate, and a water-insoluble polyacrylate.

15 13. The pharmaceutical composition according to claim 12, where the one or more than one binder is a water-insoluble polyacrylate selected from the group consisting of a water-insoluble acrylate polymer, a water-insoluble methacrylate polymer, a water-insoluble methylmethacrylate polymer, a water-insoluble ethylacrylate polymer, a copolymer comprising a combination of the preceding polymers, a water-insoluble quaternary ammonium functional group containing derivative of the preceding polymers and copolymers, and a water-insoluble ester functional group containing derivative of the preceding polymers and copolymers.

20 14. The pharmaceutical composition according to claim 13, where the one or more than one binder is a water-insoluble polyacrylate selected from the group consisting of an acrylate-methacrylate copolymer with a quaternary ammonium functional group, an ethylacrylate-methylmethacrylate copolymer with a neutral ester functional group, and an (ethylacrylate, methylmethacrylate) polymer dispersion.

25 15. A method of making a pharmaceutical composition for the controlled release of a drug in the form of a perforated tablet, the method comprising:

a) mixing one or more than one enteric polymer and a drug to form a mixture, where the enteric polymer is substantially hydrophobic and substantially soluble in a substantially

aqueous environment above a pH of about 5;

- b) compressing the mixture into a tablet; and
- c) forming a perforation in the tablet.

16. The method according to claim 15, additionally comprising mixing one or more
5 than one binder into the one or more than one enteric polymer and a drug to form the mixture.

17. A pharmaceutical composition for the controlled release of a drug in the form of a perforated tablet made according to the method of claim 15.

18. The method of making the pharmaceutical composition according to claim 1, the method comprising:

- 10 a) mixing the one or more than one enteric polymer and a drug to form a mixture;
- b) compressing the mixture into a tablet; and
- c) forming a perforation in the tablet.

19. A pharmaceutical composition for the controlled release of a drug in the form of a perforated tablet, the pharmaceutical composition comprising:

- 15 a) one or more than one outer layer comprising one or more than one substantially water-insoluble polymer, or one or more than one substantially water-soluble polymer; and
- b) an inner layer comprising one or more than one enteric polymer and a drug;

where the enteric polymer is substantially hydrophobic and substantially soluble in an aqueous environment above a pH of about 5.

20 20. The pharmaceutical composition according to claim 19, where the form of the perforated tablet is a cylindrically shaped tablet, and where the perforation extends completely through the center of the cylindrically shaped tablet.

21. The pharmaceutical composition according to claim 19, where the one or more than one enteric polymer is selected from the group consisting of a
25 hydroxypropylmethylcellulose acetate succinate, a hydroxypropylmethylcellulose phthalate, a polyvinylacetate, and a polyacrylate.

22. The pharmaceutical composition according to claim 21, where the one or more than one enteric polymer is a polyacrylate selected from the group consisting of an acrylate

polymer, a methacrylate polymer, a methylmethacrylate polymer, an ethylacrylate polymer, a copolymer comprising a combination of the preceding polymers, and a carboxylic acid functional group containing derivative of the preceding polymers and copolymers.

23. The pharmaceutical composition according to claim 22, where the one or more
5 than one enteric polymer is a polyacrylate selected from the group consisting of a methacrylic acid-methylmethacrylate copolymer and a methacrylic acid-ethylacrylate copolymer.

24. The pharmaceutical composition according to claim 19, where the one or more
than one enteric polymer is present in an amount effective to control the release of the drug at a substantially constant linear rate over time, or a slightly increasing linear rate over time, or a
10 slightly decreasing linear rate over time.

25. The pharmaceutical composition according to claim 19, where the enteric polymer is present in an amount of between about 1% and about 99%.

26. The pharmaceutical composition according to claim 19, where the enteric polymer is present in an amount of between about 20% and about 75%.

15 27. The pharmaceutical composition according to claim 19, where the enteric polymer is present in an amount of between about 35% and about 65%.

28. The pharmaceutical composition according to claim 19, where the inner layer further comprises one or more than one binder.

29. The pharmaceutical composition according to claim 28, where the binder is
20 selected from the group consisting of a water-soluble cellulose, a polyethylene oxide, a polyethylene glycol, a water-insoluble cellulose, and a water-insoluble polyvinylacetate, a water-insoluble polyacrylate.

30. The pharmaceutical composition according to claim 29, where the one or more
than one binder is a water-insoluble polyacrylate selected from the group consisting of a water-
25 insoluble acrylate polymer, a water-insoluble methacrylate polymer, a water-insoluble methylmethacrylate polymer, a water-insoluble ethylacrylate polymer, a copolymer comprising a combination of the preceding polymers, a water-insoluble quaternary ammonium functional group containing derivative of the preceding polymers and copolymers, and a water-insoluble

ester functional group containing derivative of the preceding polymers and copolymers.

31. The pharmaceutical composition according to claim 30, where the one or more than one binder is a water-insoluble polyacrylate selected from the group consisting of an acrylate-methacrylate copolymer with a quaternary ammonium functional group, an
5 ethylacrylate-methylmethacrylate copolymer with a neutral ester functional group, and an (ethylacrylate, methylmethacrylate) polymer dispersion.

32. The pharmaceutical composition according to claim 19, where the outer layer comprises one or more than one substantially water-insoluble polymer selected from the group consisting of a water-insoluble ethylcellulose, a water-insoluble cellulose ester, a water-
10 insoluble polyvinylacetate, and a water-insoluble polyacrylate.

33. The pharmaceutical composition according to claim 32, where the outer layer comprises one or more than one water-insoluble polyacrylate selected from the group consisting of a water-insoluble acrylate polymer, a water-insoluble methacrylate polymer, a water-insoluble methylmethacrylate polymer, a water-insoluble ethylacrylate polymer,
15 copolymers comprising a combination of the preceding polymers, a water-insoluble quaternary ammonium functional group containing derivative of the preceding polymers and copolymers, and a water-insoluble ester functional group containing derivative of the preceding polymers and copolymers.

34. The pharmaceutical composition according to claim 33, where the outer layer
20 comprises one or more than one water-insoluble polyacrylate selected from the group consisting of an acrylate-methacrylate copolymer with a quaternary ammonium functional group, an ethylacrylate-methylmethacrylate copolymer with a neutral ester functional group, and an (ethylacrylate, methylmethacrylate) polymer dispersion.

35. The pharmaceutical composition according to claim 19, where the outer layer
25 comprises one or more than one substantially water-soluble polymer selected from the group consisting of a water-soluble cellulose, a water-soluble polyethylene oxide, and a polysaccharide.

36. A method of making a pharmaceutical composition for the controlled release of a

drug in the form of a perforated tablet comprising one or more than one outer layer comprising one or more than one substantially water-insoluble polymer, or one or more than one substantially water-soluble polymer; and an inner layer comprising one or more than one enteric polymer and a drug, where the enteric polymer is hydrophobic and substantially soluble

5 in an aqueous environment above a pH of about 5, the method comprising

a) compressing a first outer layer into a die;

b) mixing an inner layer comprising one or more than one enteric polymer and a drug to form an inner layer mixture;

c) compressing the inner layer mixture into the first outer layer;

10 d) compressing a second outer layer into the inner layer mixture to form a tablet; and

e) forming a perforation in the tablet.

37. The method according to claim 36, additionally comprising mixing one or more than one binder into the mixture comprising the one or more than one enteric polymer and a drug to form the mixture.

15 38. A pharmaceutical composition for the controlled release of a drug in the form of a perforated tablet made according to the method of claim 36.

39. The method of making the pharmaceutical composition according to claim 19, the method comprising:

a) compressing the first outer polymer layer into a die;

20 b) mixing the inner layer comprising the one or more than one enteric polymer and the drug into an inner layer mixture;

c) compressing the inner layer mixture into the first outer layer;

d) compressing the second outer polymer layer into the inner layer mixture to form a tablet; and

25 e) forming a perforation in the tablet.